UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ROBIN MARIE WARREN and
LONNY WARREN,

Plaintiffs,

v. Case No: 8:19-cv-2657-T-60JSS

C. R. BARD, INC.,

Defendant.

ORDER GRANTING IN PART, AND DENYING IN PART, "DEFENDANT C. R. BARD'S MOTION TO EXCLUDE OR LIMIT CERTAIN OPINIONS AND TESTIMONY OF RALPH ZIPPER, M.D."

This matter is before the Court on "Defendant C. R. Bard's Motion to Exclude or Limit Certain Opinions and Testimony of Ralph Zipper, M.D." and its memorandum in support, filed on May 13, 2019. (Docs. 37; 38). On May 24, 2019, Plaintiffs Robin Marie Warren and Lonny Warren filed their response in opposition to the motion. (Doc. 46). On June 3, 2019, Defendant filed a reply. The Court held a hearing to address this matter on February 19, 2020. (Doc. 71). After reviewing the motion, response, reply, court file, and record, the Court finds as follows:

Background

This case is one of thousands of similar cases filed since approximately October 2010.[1] Plaintiffs Robin Marie Warren and Lonny Warren directly filed this

[1] In the seven MDLs, over 100,000 cases have been filed, approximately 15,000 of which are in the Bard MDL. *See* MDL 2187 (C.R. Bard) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2187; MDL 2325 (American Medical Systems) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2325;

product liability case in the Southern District of West Virginia as part of the multidistrict litigation ("MDL") entitled *In re: C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187. The case was not resolved by the MDL transferee court ("MDL Court"), and it was transferred at the conclusion of the coordinated pretrial proceedings as part of Wave 8.

On February 21, 2011, Ms. Warren was implanted with the Avaulta Solo Anterior Synthetic Support System ("Avaulta") device at a hospital in Brooksville, Florida. The Avaulta device was designed and manufactured by Defendant. On April 28, 2016, Plaintiffs filed suit directly in the MDL using a short-form complaint, alleging the following claims: Negligence (Count I), Strict Liability – Design Defect (Count II), Strict Liability – Manufacturing Defect (Count III), Strict Liability – Failure to Warn (Count IV), Breach of Express Warranty (Count V), Breach of Implied Warranty (Count VI), Loss of Consortium (Count VII), and Punitive Damages (Count VIII).

In the motion before this Court, Defendant raises various *Daubert*[2] challenges to the proposed testimony of Dr. Ralph Zipper, M.D. This is not the first case where Dr. Zipper has been proposed as an expert witness. And this is not the first time Defendant has raised similar *Daubert* challenges to his testimony.

MDL 2326 (Boston Scientific) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2326; MDL 2327 (Johnson & Johnson, Ethicon) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2327; MDL 2387 (Coloplast) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2387; MDL 2440 (Cook Medical) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2440; and MDL 2511 (Neomedic) Member List of Cases, https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2511.

[2] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

Indeed, at earlier points in the MDL litigation, Defendant made some of the exact same *Daubert* arguments it makes here in an attempt to exclude Dr. Zipper's opinions. Nonetheless, Dr. Zipper was previously qualified as an expert witness in the MDL litigation. *See, e.g.*, *Piper v. C.R. Bard, Inc.*, No. 2:16-cv-11811, 2018 WL 700798, at *2–*3 (S.D.W. Va. Feb. 2, 2018); *Dennis v. C.R. Bard*, No: 2:16-cv-10815, 2018 WL 691341, at *2–*3 (S.D.W. Va. Feb. 1, 2018).

Legal Standard

An expert witness may testify in the form of an opinion if "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

Functioning as a gatekeeper, the district court plays an important role by ensuring that all scientific testimony is relevant and reliable. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W. Va. 2013). Although *Daubert* references specific factors for the district court to consider when evaluating relevancy and reliability, "[t]he inquiry to be undertaken by the district court is a flexible one focusing on the principles and methodology employed by the expert, not on the conclusions reached." *Id.* at 601–02 (internal quotations and citations omitted).

Analysis

General Causation Opinions

Defendant seeks to exclude all of Dr. Zipper's general opinions because he was not designated as a general causation expert. In their response, Plaintiffs acknowledge the MDL Court's prior rulings and indicate that they do not intend to elicit testimony from Dr. Zipper related to: general opinions on product design and polypropylene characteristics, general opinions on the FDA's 510(K) clearance process, and unrelated opinions regarding the Bard Align device.

Based on Plaintiffs' concessions and the MDL Court's prior Orders, the Court grants Defendant's motion to the extent that it will exclude Dr. Zipper's general opinions on product design and polypropylene characteristics, general opinions on the FDA's 510(K) clearance process, and unrelated opinions regarding the Bard Align device. Dr. Zipper may not offer broad testimony about the sort of harm that pelvic mesh can allegedly cause. However, Dr. Zipper is not precluded from providing case-specific opinions that connect Ms. Warren's injuries to the defective product. *See Piper,* 2018 WL 700798, at *2; *Dennis*, 2018 WL 691341, at *2.

Opinions Related to Vaginal Dysbiosis

In its motion, Defendant argues that the Court should exclude Dr. Zipper's opinions regarding vaginal dysbiosis because they are unreliable and not supported by case-specific facts. Plaintiffs, however, claim that Dr. Zipper's report clearly cites facts specific to Ms. Warren, which support his case-specific opinion related to vaginal dysbiosis. *See* (Doc. 46-1 at 29–36). Upon review, the Court finds that Dr.

Zipper's opinion is sufficiently grounded. His report includes case-specific facts related to vaginal dysbiosis. As such, Defendant's motion to preclude Dr. Zipper's opinions related to vaginal dysbiosis is denied. If Defendant believes the challenged opinion is deficient, it may attack that opinion on cross-examination.

Instructions for Use

Defendant contends that the Court should preclude Dr. Zipper from rendering opinions concerning the Avaulta Instructions for Use ("IFU"). Plaintiffs assert that in line with the MDL Court's prior rulings, Dr. Zipper will not opine as to whether the Avaulta labeling conformed to FDA requirements or what the Avaulta IFU should have contained. The MDL Court previously found that medical experts – without additional expertise in the specific area of product warnings – are not qualified to opine on the adequacy of the warnings. *See Wise v. C.R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015); *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220671, at *5 (S.D.W. Va. Sept. 5, 2018). The Court sees no reason to depart from these rulings. However, as a practicing physician, Dr. Zipper is "qualified to testify about whether the risks he perceives are in fact warned about in the IFU." *See id; see also Wise*, 2015 WL 521202, at *14.

To the extent that Defendant argues Dr. Zipper's opinion regarding the failure to warn is speculative and unreliable because it contradicts the testimony of the implanting physician, the Court notes that Plaintiffs have maintained they do not intend to elicit testimony from Dr. Zipper regarding the implanting physician's

state of mind. However, the MDL Court previously found that Dr. Zipper is qualified to testify about "factual issues or the knowledge of the medical community in general," and the Court sees no reason to depart from this ruling. *See Piper,* 2018 WL 700798, at *2; *Dennis,* 2018 WL 691341, at *3. Consequently, Defendant's motion is granted in part, and denied in part, as to Dr. Zipper's opinions concerning the Avaulta IFU.

Safer Alternatives to the Avaulta

Defendant seeks to exclude Dr. Zipper's opinion that there were safer alternatives to the Avaulta device to treat Ms. Warren. In other cases in this MDL, plaintiffs have been able to present expert evidence on safer alternative designs, including that the Avaulta product could have been designed with "polypropylene mesh with larger pores," or "rounder, thinner arms," or that the mesh could have been constructed with "native tissue." *See Dalton v. C. R. Bard, Inc.,* No. 3:19-CV-2484-D, 2020 WL 1307965, at *10–11 (N.D. Tex. Mar. 19, 2020); *Dahse v. C. R. Bard, Inc.*, No. 2:12-CV-02701, 2016 WL 7155770, at *4 (S.D. Va. Dec. 7, 2016). Consequently, Defendant's request to exclude Dr. Zipper's opinions as to safer alternatives is denied.

Legal Conclusions

In its motion, Defendant argues that Dr. Zipper should be prohibited from providing any legal conclusions, including that the product was "defective" and "unreasonably dangerous." In their response, Plaintiffs acknowledge the MDL Court's prior ruling and assert that they do not intend to elicit opinions that draw a

legal conclusion. Accordingly, Defendant's motion is granted as to this issue. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 611. Dr. Zipper is not precluded from offering testimony that uses terms that do not have a separate, distinct, and specialized meaning in the law.

State of Mind Opinions

Defendant contends that the Court should preclude Dr. Zipper from providing state of mind opinions. In their response, Plaintiffs indicate that they understand the MDL Court's prior ruling on this issue and claim that they do not intend to elicit opinions on others' state of mind. As such, Defendant's motion is granted to the extent that Dr. Zipper may not testify about what other parties did or did not know. However, the MDL Court previously found that Dr. Zipper is qualified to testify about "factual issues or the knowledge of the medical community in general," and the Court sees no reason to depart from this ruling. *See Piper,* 2018 WL 700798, at *2; *Dennis,* 2018 WL 691341, at *3.

Possible Future Adverse Events

Defendant seeks to exclude Dr. Zipper's opinions concerning possible future adverse events. Plaintiffs argue that these opinions are helpful to the jury, reliable, and admissible. Upon review of the record, the Court finds that Dr. Zipper's opinions on future possible complications are supported by the record, sufficiently grounded, and admissible. *See Dennis,* 2018 WL 691341, at *3. As such, Defendant's motion is denied as to this issue.

Accordingly, it is

ORDERED, ADJUDGED and **DECREED**:

"Defendant C. R. Bard's Motion to Exclude or Limit Certain Opinions and Testimony of Ralph Zipper, M.D" (Doc. 37) is hereby **GRANTED IN PART** and **DENIED IN PART**, as set forth herein.

DONE and **ORDERED** in Chambers, in Tampa, Florida, this 17th day of April, 2020.

TOM BARBER
UNITED STATES DISTRICT JUDGE